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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/669,817	09/26/2000	Joseph R. Byrum	38-21(51469)B	5384

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EXAMINER	
MEHTA, ASHWIN D	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/669,817	BYRUM ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 10-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 10-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on March 29, 2006 has been entered. Applicants are notified that the appeal may be resubmitted, as the claims have been twice rejected and are rejected in this first Office action following the RCE submission. See MPEP 1204.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1, 2, and 10-15 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, for the reasons of record stated in the previous Office actions.

The claims are drawn towards any substantially purified nucleic acid molecule that encodes any plant protein comprising a nucleic acid sequence from SEQ ID NO: 4, wherein said substantially purified nucleic acid molecule is greater than 60% free from other molecules

present in a natural mixture; or wherein said plant protein is a rice protein; or a substantially purified nucleic acid molecule comprising a nucleic acid sequence from SEQ ID NO: 4 or complement thereof, wherein said substantially purified nucleic acid molecule is greater than 60% free from other molecules present in a natural mixture; or a substantially purified nucleic acid molecule consisting a nucleic acid sequence from SEQ ID NO: 4 or complement thereof, wherein said substantially purified nucleic acid molecule is greater than 60% free from other molecules present in a natural mixture; or a substantially purified nucleic acid molecule comprising a nucleic acid sequence having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 4 or complement thereof, wherein said substantially purified nucleic acid molecule is greater than 60% free from other molecules present in a natural mixture.

The specification discloses 43,701 nucleic acid sequences that are EST nucleic acid molecules, including SEQ ID NO: 4 (page 16, lines 1-6, sequence listing). The nucleic acid sequences were derived from rice cDNA libraries (page 33, lines 4-7; Example 1, pages 84-87). The specification generally indicates that the disclosed ESTs can be used to acquire genes whose encoded proteins are involved in various plant processes (page 33, lines 4-26), or to acquire promoters or cis-regulatory elements, or to generally obtain nucleic acid molecules from other organisms (page 34, line 1 to page 35, line 10). No particular use is disclosed for any putative protein encoded by SEQ ID NO: 4.

The claimed nucleic acid molecule is not supported by a specific asserted utility because the disclosed use of the nucleic acid is generally applicable to any nucleic acid and therefore is not particular to the claimed molecule. Further, the claimed nucleic acid molecule is not

supported by a substantially utility because the specification states only that the EST is useful as a probe or primer in isolating other unspecific genes or regulatory regions of genes. Once such a gene is isolated and the protein obtained, further basic research would need to be conducted to characterize it. A starting material that can only be used to produce a final product does not have a substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins or regulatory regions that are to be produced as final products resulting from processes involving the claimed nucleic acid molecules have asserted or identified specific and substantial utilities. Identifying and studying the properties of the protein itself or the mechanisms in which the protein or regulatory region is involved does not define a "real world" context of use. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for SEQ ID NO: 4 such that another non-asserted utility would be well established for the compounds.

Applicants appealed the rejection to the Board of Patent Appeals and Interference and filed an Appeal Brief on March 10, 2005, but filed an RCE before a decision was rendered.

Applicants argue that specification teaches identifiable benefits for the claimed nucleic acid, for example the use in identifying the presence or absence of a polymorphism and use a marker (Appeal Brief, page 5, 2nd full paragraph to page 9, 1st full paragraph). However, the specification does not teach what the presence or absence of the polymorphism signifies. The specification indicates that polymorphisms are useful to define genetic distances or physical distances between polymorphic traits (page 45, lies 10-11). However, the specification does not

teach what these traits are. The specification does not associate the presence or absence of any polymorphism with any particular condition or state. The specification generally discusses how any of the disclosed ESTs in the sequence listing can be used to detect polymorphisms, and how to do so (page 38, line 11 to page 45, line 21). But it does not explain why SEQ ID NO: 4 particularly would be useful in detecting polymorphisms. Polymorphisms are natural variations within sequences which themselves may not have any meaningful use. Therefore, determining whether the claimed nucleic acids, or the nucleic acids detected by the claimed nucleic acids, have or do not have a polymorphism would require determining whether there was a polymorphism within such a sequence, and then determining how to use this information in a patentably meaningful way.

The Appellant also argues that many of the disclosed utilities, including the detection of polymorphism, are directly analogous to the utilities of a microscope (Appeal Brief, page 8, 1st full paragraph). This argument has been reviewed but is not convincing because the microscope provides information to the scientist that is automatically useful. For example, the microscope may be used for identification and differentiation between gram-positive and gram-negative bacteria. The differentiation of bacteria facilitates in the administration of proper antibiotics. For example, use of a microscope to determine whether Staph is present or whether Strep is present provides valuable information to the scientist and/or doctor for treating patients. The instant invention, however, provides no information to this extent. If the scientist determines that SEQ ID NO: 4 is present, one skilled in the art does not know how to use this information. Thus, the identification of SEQ ID NO: 4 is not a substantial utility. Applicants also argue that the fact that a microscope can be used for learning products or processes does not

lessen the fact that such tools have legal utility. Applicants also draw analogy to the use of a gas chromatograph to analyze the composition of a gas (Appeal Brief, page 8, 1st and 2nd full paragraphs). However, in the instant case the specification does not even identify the products or processes that SEQ ID NO: 4 can be used to study.

Applicants also argue that the claimed nucleic acid molecules can be used as probes for other molecules or as a source of primers, to isolate nucleic acid molecules of other plants and organisms (Appeal Brief, page 9, 1st full paragraph). However, the specification does not teach the substantial use of such nucleic acid molecules of the other organisms. The specification does not teach any property of SEQ ID NO: 4 or any phenotype that is affected by it. In the absence of this information, using the claimed nucleic acid molecules as probes would only lead to the isolation of other nucleic acid molecules that lack substantial utility.

Applicants also argue that the specification indicates that the claimed nucleic acid molecule can be used to initiate a chromosome walk, to isolate a promoter (Appeal Brief, paragraph bridging pages 9-10). Applicants argue that the Examiner's position, that utility is lacking because other nucleic acid molecules can be used for the same purpose, is wrong because there is no requirement of exclusive utility in patent law. Applicants cite the decision of *Carl Zeiss Stiftung v. Renshaw PLC* in support, for stating that an invention need not be the best or only way to accomplish a certain result (Appeal Brief, page 10, 1st full paragraph). However, the Examiner has not stated that the invention needs to be the best or only way to accomplish a certain result. The specification does not teach what the certain result is for the utility of the instant invention. The specification does not provide any expectation of successfully using SEQ ID NO: 4 to isolate promoters. Applicants also argue that the Examiner's position indicates that

a new golf club has no legal utility because other golf clubs can be used to hit golf balls (response, page 10, 1st full paragraph). However, not every utility will satisfy 35 U.S.C. 101, even if the utility is shared with other things. For example, the utility of using a transgenic mouse as snake food is neither specific nor substantial because all mice can have this function.

Applicants argue that it is incorrect that the use of the claimed nucleic acid molecule in a chromosome walk is not specific, because they provide a particularly appropriate and demonstrably useful starting point, and that a random nucleic acid does not provide an equally good starting point (Appeal Brief, paragraph bridging pages 10-11). However, the specification does not demonstrate how SEQ ID NO: 4 provides a particularly appropriate and useful starting point. There is no evidence or expectation that the claimed nucleic acid molecules would be effective at all in a chromosome walk to isolate a promoter.

Applicants argue that the claimed nucleic acid molecules provide immediate benefit to the public in their use in detecting the presence or absence of polymorphisms, in that polymorphisms enable a plant breeder to determine the distribution of a parental genetic material in the progeny of a cross (Appeal Brief, paragraph bridging pages 11-12). However, the utility of the claimed nucleic acid molecules for detecting polymorphisms is not a substantial utility, for the reasons discussed above. Further, any unique nucleic acid sequence can be used to follow plants in a breeding program. Applicants also argue that the utility of EST sequences is self-evident from the growth of a multi-million dollar industry in the United States premised on their usefulness (Appeal Brief, page 12, 1st and 2nd paragraphs). However, Applicants have not provided any suggestion about which use of ESTs the industry is premised on. The specification only goes so far as to speculate how the ESTs can be useful. Further basic research is required,

even in the EST industry, to determine the specific and substantial utility of SEQ ID NO: 4. The use of SEQ ID NO: 4 is not clear, disclosed, well-established, specific, or substantial. The U.S. Supreme Court in *Brenner v. Manson, Supreme Court of the U.S. 148 USPQ 689 (1966)* made it clear that to meet the utility requirement under 35 U.S.C. 101, an invention must be useful in its currently available form, by indicating, "This is not to say that we mean to disparage the importance of contributions to the fund of scientific information [383 U.S. 519, 536] short of the invention of something "useful," or that we are blind to the prospect that what now seems without "use" may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It's not a reward for the search, but compensation for its successful conclusion." The instant application provides only a starting point for the hunt. It does not reach a conclusion.

Further, the U.S. Court of Appeals for the Federal Circuit recently agreed that the uses for ESTs, including those discussed above, did not meet the utility requirement. See *In re Fisher*, 76 USPQ2d 1225 (CA FC 2005).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 2, and 10-15 remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not

know how to use the claimed invention, for the reasons of record stated in the previous Office actions.

The U.S. Court of Appeals for the Federal Circuit also recently agreed that the enablement requirement is not met when the claimed invention does not have a specific and substantial utility. See *In re Fisher*, 76 USPQ2d 1225 (CA FC 2005).

Further, SEQ ID NO: 4 is a partial cDNA sequence, does not encode a complete protein, and is not predictive of the remaining sequences of the complete cDNA. As the function of the claimed nucleic acid molecule, or the protein it encodes, is not taught, one skilled in the art therefore would not know how to use it. Undue experimentation would be required by one skilled in the art to determine the remaining nucleotide sequences of the coding region that SEQ ID NO: 4 is a part of, and characterize the function of the encoded product. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. Also see In re Bell, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Deuel, 34 UPSQ2d, 1210 (Fed. Cir. 1995), which teach that the mere existence of a protein does not enable claims drawn to a nucleic acid encoding that protein. See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Applicants appealed the rejection to the Board of Patent Appeals and Interference and filed an Appeal Brief on March 10, 2005, but filed an RCE before a decision was rendered.

Applicants argue that the rejection is erroneous and has been overcome by the arguments regarding utility because it is well-established law that the enablement requirement is met if the description enables any mode of making and using the invention (Appeal Brief, page 14, 1st full paragraph). However, the utility requirements of 35 U.S.C. 101 have not been met for the claimed invention, for the reasons discussed above. The specification therefore does not enable one skilled in the art in the use of the invention.

Applicants also argue that an analysis of the criteria presented by *In re Wands* supports their position. Applicants argue that, for the criterion of quantity of experimentation necessary, that the quantum of experimentation is reduced by the knowledge of conservative nucleotide substitutions, identification of active site, and conserved regulatory elements (Appeal Brief, paragraph bridging pages 14-15). However, the nucleotide sequence of the open reading frame to which SEQ ID NO: 4 belongs is unknown. It is not clear how, in the absence of that information, one can predict or identify an active site, or perform other assays. Applicants argue that sufficient guidance is provided by the disclosure, which sets forth nucleic acid molecules and method of use thereof in the production of transgenic cells and plants, and that the performance of well-known steps such as sequence alignment cannot create undue experimentation (Appeal Brief, paragraph bridging pages 14-15). However, in the absence of the effect that SEQ ID NO: 4 has on a plant or cell, one skilled in the art would not know how to use transgenic cells and plants comprising it. Further, a sequence alignment would not provide

conclusive data regarding the remaining sequences of the open reading frame that comprises SEQ ID NO: 4.

Applicants argue, regarding amount of direction or guidance given, that the specification provides evidence of sequence identity, discloses the identification of promoter regions associated with the claimed nucleic acid molecule, and discusses use of the claimed nucleic acid molecule to isolate additional sequences within a genome (Appeal Brief, page 15, 1st full paragraph). However, contrary to Applicants' assertion, the specification does not identify promoter regions associated with the claimed nucleic acid molecules. Further, in the absence of the function of SEQ ID NO: 4, undue experimentation would be required by one skilled in the art to determine how to use additional sequences isolated by using the claimed nucleic acid molecule.

Applicants assert that the fourth, fifth and sixth Wands criteria focus on the nature of the invention, state of the art, and relative skill in the art, and argue that the invention relates to nucleic acid sequences, that the specification describes amino acid sequences derived from them, antibodies, constructs, methods related thereto, and that practitioners of the art are guided by resources that can be used to identify, confirm and introduce into other hosts, nucleic acid and amino acid sequences (Appeal Brief, paragraph bridging pages 15-16). However, the specification does not teach how one would use a transgenic host transformed with the claimed nucleic acid molecules. The specification does not teach how one skilled in the art would identify and confirm that a nucleic acid homologue has been isolated when the function of the open reading frame that SEQ ID NO: 4 belongs to has not been taught.

The seventh Wands criteria pertains to predictability of the art, and Applicants argue that the Examiner has not provided evidence why one skilled in the art would not be able to predict conservative substitutions or use the nucleic acid molecules in the disclosed uses (response, page 16, 1st full paragraph). However, again, the specification does not teach how one skilled in the art would use any nucleic acid molecules that have been isolated using the claimed nucleic acid molecules, since the function of SEQ ID NO: 4 is unknown. What trait is conferred to a transgenic plant into which SEQ ID NO: 4 has been introduced, for example? Further, the correct reading frame of SEQ ID NO: 4 cannot be confirmed in the absence of the remainder of the open reading frame.

The eighth criterion focuses on breadth of the claims, and Applicants argue that one of skill in the art is specifically guided by the disclosure to look to sequence identity to determine which species among those encompassed by the claimed genus possess the disclosed utility (Appeal Brief, page 16, 2nd full paragraph). It appears that Applicants are addressing those claimed molecules that comprise a nucleic acid molecule that share less than 100% sequence identity with SEQ ID NO: 4. However, one skilled in the art cannot determine if all of the claimed nucleic acid molecules share the same function as SEQ ID NO: 4, in the absence of knowledge of the function of SEQ ID NO: 4.

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

4. Claims 1-2, 10, and 12-15 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn towards any substantially purified nucleic acid molecule that encodes any plant protein comprising a nucleic acid sequence from SEQ ID NO: 4, wherein said substantially purified nucleic acid molecule is greater than 60% free from other molecules present in a natural mixture; or wherein said plant protein is a rice protein; or a substantially purified nucleic acid molecule comprising a nucleic acid sequence from SEQ ID NO: 4 or complement thereof, wherein said substantially purified nucleic acid molecule is greater than 60% free from other molecules present in a natural mixture; or a substantially purified nucleic acid molecule comprising a nucleic acid sequence having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 4 or complement thereof, wherein said substantially purified nucleic acid molecule is greater than 60% free from other molecules present in a natural mixture.

The specification discloses 43,701 nucleic acid sequences that are EST nucleic acid molecules (page 16, lines 1-6, sequence listing). The nucleic acid sequences were derived from rice cDNA libraries (page 33, lines 4-7; Example 1, pages 84-87). Here, the nucleic acid sequence of SEQ ID NO: 4 is the elected invention. The specification indicates that the disclosed ESTs can be used to acquire genes whose encoded proteins are involved in various plant processes (page 33, lines 4-26), or acquire promoters or cis-regulatory elements, or to

generally obtain nucleic acid molecules from other organisms (page 34, line 1 to page 35, line 10). No particular use is disclosed for any of putative protein encoded by SEQ ID NO: 4.

A review of the full content of the specification indicates that SEQ ID NO: 4 is essential to the claimed invention. A review of the language of claim 1 indicates that the claim is drawn to a genus- any substantially purified nucleic acid molecule encoding any plant protein, or fragment thereof, comprising the nucleotide sequence in SEQ ID NO: 4, wherein said molecule is greater than 60% free from other molecules present in a natural mixture. Dependent claim 2 limits the plant protein to be from rice. Claim 10 also encompasses a broad genus- all substantially purified nucleic acid molecules comprising SEQ ID NO: 4 or complement thereof, wherein said molecule is greater than 60% free from other molecules present in a natural mixture. A search indicates that the nucleotide sequence set forth in SEQ ID NO: 4 is novel and unobvious.

There is a single species explicitly disclosed- the nucleotide sequence consisting of SEQ ID NO: 4.

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. The present claim encompasses full-length genes and cDNAs that are not further described. There is substantial variability among the species of DNAs encompassed within the scope of the claims because SEQ ID NO: 4 is only a fragment of a cDNA. When reviewing a claim that encompasses a widely varying genus, common attributes or features shared among species of the genus must be evaluated. In the case of a partial cDNA sequence that is claimed with open language (comprising), the genus encompasses a variety of subgenera with widely varying attributes. For

example, a cDNA's principle attribute would include its complete coding region. A partial cDNA that does not include a disclosure of any complete open reading frame of which it would be a part, is not representative of the genus of cDNAs because no information regarding the coding capacity of any cDNA molecule is disclosed. Further, defining the cDNA in functional terms would not suffice in the absence of a disclosure of structural features or elements of a cDNA that would encode a protein having a stated function.

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Col.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Here, the specification discloses only a single common structural feature shared by members of the claimed genus, i.e., SEQ ID NO: 4. Since the claimed genus encompasses genes yet to be discovered, DNA constructs that encode fragments of proteins, etc., the disclosed structural feature does not "constitute a substantial portion" of the claimed genus. Therefore, the disclosure of SEQ ID NO: 4 does not provide an adequate written description of the claimed genus.

Weighing all factors, 1) partial structure of the DNAs that comprise SEQ ID NO: 4, 2) the breadth of the claims as reading on genes yet to be discovered in addition to numerous fusion constructs and cDNAs, 3) the lack of correlation between the structure and function of the genes; in view of the level of knowledge and skill in the art, one skilled in the art would not recognize

from the disclosure that Applicants were in possession of the genus of substantially purified nucleic acid molecules which comprise SEQ ID NO: 4.

Claim 12 is drawn to a genus- all substantially purified nucleic acid molecules comprising any nucleic acid sequence having between 100% and 90% sequence identity with SEQ ID NO: 4 or complement thereof, wherein said molecule is greater than 60% free from other molecules in a natural mixture. Claims 13-15 limit the substantially purified nucleic acid molecule of claim 12 to have between 100% and 95%, 100% and 98%, and 100% and 99% sequence identity to SEQ ID NO: 4. However, the only species encompassed by the claims that is described by the specification is the nucleotide sequence of SEQ ID NO: 4. All of the other species encompass nucleic acid sequences that differ from SEQ ID NO: 4. No function is assigned to the amino acid sequence encoded by SEQ ID NO: 4. The specification has failed to correlate a function with the structures of substantially purified nucleic acid molecules sharing between 100% and 90% sequence identity with SEQ ID NO: 4.

Applicants appealed the rejection to the Board of Patent Appeals and Interference and filed an Appeal Brief on March 10, 2005, but filed an RCE before a decision was rendered.

Applicants argue that it is not proper basis to reject a claim for lack of written description because of the open language, "comprising," and that if it were, every "comprising" claim would be invalid for failing to describe every nuance of the claimed invention (Appeal Brief, paragraph bridging pages 17-18). However, Applicants have not been required to describe *every* nuance. Rather, the specification only describes a single species, the nucleotide sequence set forth in SEQ ID NO: 4.

Applicants argue that the application describes more than just SEQ ID NO: 4, for example gene sequences, corresponding sequences from other species, promoter sequences, plant homologue proteins (Appeal Brief, page 19, 1st full paragraph). However, none of these sequences are described in the specification. Applicants have not provided any full-length gene sequences. Nucleic acid sequences encoding plant homologue proteins are not described, especially given that the identity of the full-length protein encoded by the complete open-reading frame that comprises SEQ ID NO: 4 is not disclosed. The court in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), held that "An adequate written description of a DNA…'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". While Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. In the present situation, Applicants have provided only a disclosure of a wish to obtain gene sequences, homologues, and mutants comprising SEQ ID NO: 4 or sequences having 100% to 90% sequence identity to SEQ ID NO: 4.

Applicants cite the Federal Circuit decision of *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1321, 63 USPQ 2d. 1609, 1610 (Fed. Cir. 2002) in support, arguing that the court determined that "it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art" (Appeal Brief, page 20, 1st full paragraph). However, in the patent considered in the *Enzo* decision, the deposited material corresponded exactly to one of the claimed products. The appeals court remanded the case to the district court

to make findings on whether there was a correlation between the structure of the deposited material and the function of the variant material also claimed.

Applicants argue that they have disclosed a common structural feature, SEQ ID NO: 4, and that if a particular nucleic acid molecule contains SEQ ID NO: 4, then it is a member of the claimed genus (Appeal Brief, paragraph bridging pages 20-21). However, SEQ ID NO: 4 is not shared with nucleic acid molecules that comprise a sequence that has less than 100% identity to SEQ ID NO: 4, as claimed. Appellant argues that if a nucleic acid molecule contains a sequence that has 95% identity with SEQ ID NO: 4, then it is a member of the claimed genus (footnote on page 20). However, it is noted that the criteria for meeting the written description requirement is not limited to providing a means for distinguishing between molecules which fall within the claimed genus and molecules which fall outside the claimed genus. Rather, the requirement is met by providing a showing that Applicants were, at the time the application was filed, in possession of the claimed invention. Providing a statement that the invention covers nucleic acid having 90-100% identity with SEQ ID NO: 1 is not equivalent to disclosing nucleic acids which fall within the claimed genus of nucleic acids. The specification does not describe any non-coding region of any gene that comprises SEQ ID NO: 4 or variant sequences that comprise SEQ ID NO: 4, or the functions of such genes or variants.

In response to the Examiner's previous response, indicating that the functional activity of SEQ ID NO: 4 is not correlated with the claimed genus of nucleic acid molecules because the functional activity of SEQ ID NO: 4 is not provided, Applicants argue that claims 10 and 12-15 do not recite that the nucleic acid molecule encodes a plant protein (Appeal Brief, page 21, 2nd full paragraph). However, nucleic acid molecules encoding proteins are encompassed by the

claims. Further, Applicants themselves have argued that nucleic acid molecules comprising nucleic acid sequences having conservative variations or encoding amino acid sequences having conservative substitutions or plant homologue proteins are allegedly described (see Appeal Brief, page 19, 1st full paragraph).

Summary

5. Claims 1, 2, and 10-15 remain rejected.

6. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and were finally rejected on the grounds and art of record prior to the submission. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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